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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,060	03/01/2001	Kazuhiro Kaneko	0425-0825P	6946

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EXAMINER

COLE, MONIQUE T

ART UNIT	PAPER NUMBER
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1743

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DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/786,060

Applicant(s)

KANEKO ET AL.

Examin r

Monique T. Cole

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 3 & 6 are objected to because of the following informalities:
 - Claim 3, line 2 should read, "which is conducted. . .".
 - Claim 6, line 3 should read, "diameter not greater than 30 nm, is prepared. . ."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there are no steps present to correlate a relationship between membrane fluidity or circular dichroism & forecasting of the pharmacokinetics of a lipid A analog.
3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite because of the use of the term "pharmacokinetics". This term has not been clearly defined in the specification other than to be associated with membrane fluidity or circular dichroism. The term is deemed to be vague, and thus does not provide a clear

indication of Applicant's intent. If the term is thought to be inclusive of other parameters, the Examiner kindly asks Applicant to point out such support in the specification. Otherwise, further clarification and/or correction is required.

Claim 2 is rendered indefinite because it is unclear what the injection preparation is being evaluated for. How is this claim different from claim 1 which presumably evaluates the injection preparation for membrane fluidity or circular dichroism? Further clarification is required.

Claim 4 is rendered indefinite because the phrase "the preparation step" of the injection preparation. What is the "preparation step"? What does it include? Further clarification is required.

Claim 12 is rendered indefinite because it is unclear how the lipid A analog or its salt may be in the form of endoplasmic reticulum (ER) with lipid biomolecular membrane or micelle.

Does Applicant mean that the lipid A analog is found *within* the ER?

4. Claim 4 recites the limitation "the preparation step" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Allowable Subject Matter

5. Claims 1-12 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

6. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest the measurement of membrane fluidity and/or circular dichroism of lipid A-analogs and its relationship to the pharmacokinetics.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 703-305-0447. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0661.

Monique T. Cole
Examiner
Art Unit 1743

MC *MC*
April 7, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700